

### III. Remarks

#### A. Introduction

Reconsideration and allowance of the subject application are respectfully requested.

Claims 1, 2, 5 - 15, 17, and 23 - 28 are pending in the application. Claims 1, 25, and 28 are independent. Claim 2 has been amended. Support for the amendment to claim 2 can be found in Example 1 on page 11 of the Specification and in claim 2 as filed. The Specification has been amended to incorporate the subject matter of originally-filed claim 2. No new matter has been introduced by way of any of the aforementioned amendments.

#### B. The objections to the Specification should be withdrawn

The Patent Office has objected to claims 1, 2, 25, and 28 for the reasons set forth on page 2 of the Office Action.

While not acquiescing to the Patent Office's position regarding the objection to the Specification vis-à-vis the aforementioned claims, and simply in an effort to expedite the prosecution of the instant application, Applicant has amended the Specification to incorporate the subject matter of originally-filed claim 2. Applicant has also amended claim 2 to recite that the amount of pharmaceutically-acceptable excipient is about 13% by weight. That range of a pharmaceutically-acceptable excipient is fully supported by Example 1. Accordingly, Applicant offers that the objection

to the Specification has been overcome. Reconsideration and withdrawal of the objections to the Specification are respectfully requested.

C. The rejection of claims 1, 2, 5 - 15, 17, and 23 - 28 under 35 U.S.C. § 112, second paragraph should be withdrawn

Claims 1, 2, 5 - 15, 17, and 23 - 28 stand rejected under 35 U.S.C. § 112, second paragraph for the reasons set forth on page 3 of the Office Action. Applicant respectfully traverses this rejection.

The Patent Office states that the "metes and bounds" of the rejected claims are rendered unclear by the term "about."

The Patent Office states that "it is not clear what patent protection would be afforded by[, for example,] 'about 5% by weight olive oil,' when there is no information in the specification or the prior art to provide any suggestion [of] what range is covered by the term 'about'." In addition to these statements, the Patent Office cites Amgen, Inc. v. Chugai Pharm. Co., 18 U.S.P.Q.2d 1016 (Fed. Cir. 1991) in support of the notion that the term "about" generally renders claims indefinite.

Definiteness problems often arise when words of degree are used in a claim. That some claim language may not be precise, however, does not automatically render a claim indefinite, and thus invalid.<sup>1</sup> Applicant notes that many

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<sup>1</sup> *BJ Servs. Co. v. Halliburton Energy Servs. Inc.*, 67 USPQ2d 1692,

cases have held claims using the term "about" to be definite.<sup>2</sup> Further, it appears well settled that the term "about" must be given reasonable scope; that is, a scope as it would be understood by persons experienced in the field of the invention.<sup>3</sup>

Turning now to Amgen, Applicant first submits that at least one court has held that Amgen expressly rejects the sweeping proposition that the use of the term "about" renders a claim *per se* indefinite.<sup>4</sup> Applicant also submits that the holding in Amgen vis-à-vis the indefiniteness of the term "about" is that a claim reciting the term is indefinite only "[w]hen the meaning of claims is in doubt, especially when . . . there is close prior art."<sup>5</sup> In arriving at its holding, the court considered the following factors: (1) the wide range of error associated with the form of measurement (bioassays); (2) the close prior art; (3) the difficulty in

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1695 (Fed. Cir. 2003) (quoting *Seattle Box Co., Inc. v. Indus. Crating & Packing, Inc.*, 731 F.2d 818, 826 (Fed. Cir. 1984) (internal quotation marks omitted)).

2 See, e.g., *BJ Servs. Co.*, 67 USPQ2d at 1695 (claim was not invalid for indefiniteness, where claimant presented evidence that "the term 'about' is intended to encompass the range of experimental error that occurs in any measurement and that one of skill in the art would readily understand the range that 'about 0.06' was intended to include"); *Chem. Separation Tech. Inc.*, 63 USPQ2d at 1123 (citing five examples).

3 *Modine Mfg. Co. v. U.S. Int'l Trade Comm'n*, 75 F.3d 1545, 1554 (Fed. Cir. 1996), cert. denied, 518 U.S. 1005 (1996) (internal citation omitted); see also *Eiselstein v. Frank*, 52 F.3d 1035, 1040 (Fed. Cir. 1995); accord *Chem. Separation Tech. Inc.*, 63 USPQ2d at 1123 (quoting Robert L. Harmon, *Patents and the Federal Circuit* § 5.6(b) at 251 (5th ed. 2001)).

4 *Chem. Separation Tech. Inc. v. United States*, 63 USPQ2d 1114 (Fed. Cl. 2002).

5 *Amgen*, 18 USPQ2d at 1031 citing *Standard Oil Co. v. Am. Cyanamid*

determining infringing activity values, if any, between the claimed invention and the prior art (*i.e.*, between the claimed "at least about 160,000" IU/AU and the prior art value of 128,620 IU/AU); (4) the prosecution history (*i.e.*, the cancellation of the phrase "at least 120,000" from the claims); and (5) the fact that even the claimant's expert found it difficult to define "at least about 160,0000."<sup>6</sup>

Applicant submits that none of the first three applicable factors considered by the court in Amgen apply in the present case. First, there is not a wide range of error associated with the form of measurement of the components of the claimed composition. The invention is directed to a composition for treating burns and methods for treating burns using that composition. The composition comprises various components in percent-by-weight amounts. The form of measurement of the percent-by-weight amounts for each of the components of the claimed composition does not result in a wide range of error as encountered by the court in Amgen. Second, there is no prior art that discloses or suggests the claimed composition for treating burns and methods of treating burns using that composition. Applicant has, in fact, successfully distinguished the instant claims from all prior art that the Patent Office considered to allegedly render the claimed invention obvious. Finally, there is no

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Co., 227 USPQ 293, 297 (Fed.Cir. 1985).

<sup>6</sup> Amgen, 927 F.2d at 1217-18.

difficulty in determining infringing values for the percent-by-weight values for each component recited in the claimed composition. Accordingly, Applicant offers that the term "about," as used in the pending claims, is definite and fully complies with the mandates of 35 U.S.C. § 112, second paragraph. Reconsideration and withdrawal of the rejection are respectfully requested.

Applicant's undersigned attorney may be reached in our Washington, D.C. office by telephone at (202) 625-3620. All correspondence should continue to be directed to our address given below.

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